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10/507,167

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Jerzy Paszkowski

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,167

Applicant(s)

PASZKOWSKI ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-14 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-3, 9-14 in the reply filed on 10 September 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The previous restriction between Groups 1 and V is withdrawn upon reconsideration of the overlapping scope between the inventions of the groups.

Claims 4-8, 15-24 are withdrawn from consideration.

Claims 1-3, 9-14, 25-28 are under prosecution.

Claim Objections

2. a. Claims 10 and 11 are objected to under 37 CFR 1.75 as being duplicates of claims 2 and 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

b. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 appears to redefine the oligonucleotide probe segment of Claim 1. A dependent claim cannot redefine an element in an independent claim as something entirely different. Therefore, Claim 12 improperly depends from Claim 1.

Claim Rejections - 35 USC § 112

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite for the recitations "modified/blocked nucleotides/nucleosides" and "modified/blocked amino acids". The recitations are indefinite because it is unclear what is encompassed by the "/". As such, the scope of the Markush Group is undefined.

Claim 14 is indefinite because it further defines the "covalently attached" probe segments as "immobile". However, it is unclear how covalently attached probe could be anything other than "immobile". Therefore, Claim 14 does not appear to further limit the probes of Claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1, 9, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000).

Regarding Claims 1 and 9, Yasuda et al disclose a microcapillary hybridization chamber comprising a capillary having probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall (Columns 16-17).

Regarding Claim 12, Yasuda et al disclose the chamber of Claim 1 wherein the probe is a nucleic acid (Columns 16-17).

Regarding Claim 13, Yasuda et al disclose the chamber wherein the probe segment is distinguishable from other segments (Column 16, lines 37-53).

Regarding Claim 14, Yasuda et al disclose the chamber wherein the probe segment is immobile (Column 16, line 52-Column 17, line 6).

Claims 1, 9, 12-14 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by Kuhr et al (U.S. Patent No. 6,294,392, issued 25 September 2001).

Regarding Claims 1 and 9, Kuhr et al disclose a microcapillary hybridization chamber comprising a capillary having probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall (Abstract, Column 2, lines 31-66, Column 16, lines 47-60).

Regarding Claim 12, Kuhr et al disclose the chamber of Claim 1 wherein the probe is a nucleic acid, antibody, protein, peptide, hapten, ligand (Column 3, lines 63-67, Column 12, line 54-Column 16, line 37).

Regarding Claim 13, Kuhr et al disclose the chamber wherein the probe segment is distinguishable from other segments (Column 2, lines 50-57).

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Regarding Claim 14, Kuhr et al disclose the chamber wherein the probe segment is immobile (Abstract, Column 2, lines 31-66, Column 16, lines 47-60).

Claims 1, 9, 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Suyama (U.S. Patent No. 6,559,296, filed 21 February 2001).

Regarding Claims 1 and 9, Suyama discloses a microcapillary hybridization chamber comprising a capillary having probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall (Column 8, lines 5-15 and Column 9, line 36-Column 10, line 35).

Regarding Claim 12, Suyama discloses the chamber of Claim 1 wherein the probe is a nucleic acid (Abstract).

Regarding Claim 13, Suyama discloses the chamber wherein the probe segment is distinguishable from other segments (Column 8, lines 5-15).

Regarding Claim 14, Suyama discloses the chamber wherein the probe segment is immobile (Column 9, line 36-Column 10, line 35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-3, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000) in view of Suyama (U.S. Patent No. 6,559,296, filed 21 February 2001).

Regarding Claims 2-3, 10-11, Yasuda et al disclose a microcapillary hybridization chamber comprising a capillary having probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall (Columns 16-17) wherein the probe segments are closely aligned along the capillary (Column 16, lines 32-48) but the reference is silent regarding the number of segments per cm. However, capillaries having closely spaced probe segments separated by 1 μ m were well known in the art at the time the claimed invention was made as taught by Suyama (Column 8, lines 10-15).

Suyama teaches a hybridization chamber similar to that of Yasuda et al wherein the capillary has probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall and separated by 1 μ m (Column 8, lines 5-15 and Column 9, line 36-Column 10, line 35).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe segment spacing of Suyama to the capillary of Yasuda et al to provide segment densities of 500 or 1,000 segments per cm. One of ordinary skill in the art would have been motivated to do so based on the desire of Yasuda to closely immobilize the probes (Column 16, lines 38-41). Hence, it would have been obvious to use the immobilization techniques taught by Suyama to the capillaries of Yasuda so as to provide closely spaced probes (e.g. 1000 per cm) as desired by Yasuda.

Claims 2-3, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhr et al (U.S. Patent No. 6,294,392, issued 25 September 2001) in view of Suyama (U.S. Patent No. 6,559,296, filed 21 February 2001).

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Regarding Claims 1 and 9, Kuhr et al disclose a microcapillary hybridization chamber comprising a capillary having probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall (Abstract, Column 2, lines 31-66, Column 16, lines 47-60). Furthermore, Kuhr et al specifically teach the capillaries have closely spaced probe segments that can detect at least 500 different analytes (Column 2, lines 50-67) but the reference is silent regarding the number of segments per cm. However, capillaries having closely spaced probe segments separated by 1 μ m were well known in the art at the time the claimed invention was made as taught by Suyama (Column 8, lines 10-15).

Suyama teaches a hybridization chamber similar to that of Kuhr et al wherein the capillary has probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall and separated by 1 μ m (Column 8, lines 5-15 and Column 9, line 36-Column 10, line 35).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe segment spacing of Suyama to the capillary of Kuhr et al to provide segment densities of 500 or 1,000 segments per cm. One of ordinary skill in the art would have been motivated to do so based on the desire of Kuhr to closely immobilize the probes for the detection of at least 500 analytes (Column 2, lines 50-67). Hence, it would have been obvious to use the immobilization techniques taught by Suyama to the capillaries of Kuhr so as to provide closely spaced probes (e.g. 1000 per cm) as desired by Kuhr.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, issued 25 July 2000) in view of Shalon et al (U.S. Patent Application Publication No. 2001/0051344, published 13 December 2001).

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Regarding Claim 25, Yasuda et al teaches an apparatus for hybridization detection, the apparatus comprising a microcapillary hybridization chamber comprising a capillary having probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall (Columns 16-17), a detector for detecting hybridization within the capillary (#444), a computer system (#400) coupled to the detector and comprising a program (Column 17, lines 20-54). Yasuda further teach the computer system collects and processes data from the processor using techniques known in the art (Column 17, lines 30-34) but the reference does not specifically teach a program for displaying detected signal data.

Regarding Claim 26, Yasuda et al teach the detector comprises excitation optics for focusing light on probe segments (#442, Column 17, line s37-41).

Regarding Claim 27-28, Yasuda teaches the computer system collects and processes data from the processor using techniques known in the art (Column 17, lines 30-34) but does not teach fluorescence intensity determination, removing data outliers, calculating binding affinity or probe color display.

However, programmed detection of hybridization signals were well know and routinely practiced as suggested by Yasuda and as taught by Shalon et al (§ 202).

Shalon teaches the processor determines the intensity of fluorescence, removal of outliers based on normalization calibrations, determines relative binding affinity and displays color signals (§ 149-150, 196-204) whereby the signals are analyzed digitally to quantitatively measure hybridization reactions (§ 202-204). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the programmed analysis of Shalon to the computer processing of Yasuda. One of ordinary skill in the art would have been motivated to do so based on the suggestion of Yasuda and further for the expected benefit of obtaining quantitative measurement of hybridization reactions as taught by Shalon (§ 202-204).

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

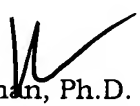
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 14, 2007